Supreme Court, U.S.
FILED
JUL 31 1997
CLERK

No. 97-26

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND THOMAS EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG CO. AND DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

BRIEF OF RESPONDENT DR. JAMES H. LETHAM, O.D., IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

ROBERT J. BEHLING
Counsel of Record
BRIAN S. KANE
JEANETTE H. HO
PIETRAGALLO, BOSICK & GORDON
One Oxford Centre, 38th Floor
Pittsburgh, PA 15219
(412) 263-2000
Counsel for Respondent Dr. James H. Letham, O.D.

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39pp

EDITOR'S NOTE

THE FOLLOWING PAGES WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) mandates preemption of state common law claims which seek to impose requirements which would conflict with the requirements imposed by the Food and Drug Administration in the course of the pre-market approval process?

STATEMENT OF THE CASE

Petitioners filed the suit which gives rise to this Petition for Writ of Certiorari on September 9, 1992 seeking to recover for damages allegedly sustained as a result of using contact lens cleaner and solution manufactured by Respondent, Polymer Technology Corporation ("Polymer") and sold by Respondent, Thrift Drug, Inc. ("Thrift Drug"). Wife-Petitioner alleges that she developed acanthamoeba keratitis as a result of rinsing her contact lenses with tap water as required by the directions which accompanied the sale of the cleaner and solution.

Between September 16 and September 25, 1990, Wife-Petitioner was a patient of Respondent, Dr. James H. Letham, an optometrist. Plaintiff was a patient of Dr. Letham for several years prior to this incident. On or about September 16, 1990, Dr. Letham examined the Wife-Petitioner and prescribed a gas permeable right contact lens manufactured by Respondent, Polymer. Dr. Letham fitted the lens and provided Wife-Petitioner with a starter kit supplied to Dr. Letham by Polymer. The starter kit contained small, sample-sized containers of cleaner and solution also manufactured by Polymer. Wife-Petitioner eventually purchased a larger bottle of the cleaner and solution from Thrift Drug.

The cleaner and solution contained explicit instruction for the proper use of the products. These directions were approved by the Food and Drug Administration ("FDA") prior to the introduction of these products into the open market. *See* Affidavit of William Gleason, O.D., which is attached at S.A. 1.

Petitioners have asserted claims of negligence, strict liability and breach of implied warranties against Dr. Letham. Essentially, Petitioners contend that Dr. Letham is liable for failing to warn or instruct the Wife-Petitioner on the use of the cleaner and solution or that she could develop acanthamoeba keratitis through the use of the cleaner and solution manufactured by Polymer.

REASONS WHY THE PETITION FOR WRIT OF CERTIORARI SHOULD BE DENIED

Dr. James Letham is Not a Proper Respondent to this Petition

The only question presented by Petitioners in this Petition for Writ of Certiorari is "[w]hether 21 U.S.C. § 360k(a) mandates preemption of all state law causes of action for injuries caused by medical devices which have received pre-market approval from the Food and Drug Administration?" *See* Petition for Writ of Certiorari, p. i.

By order dated October 24, 1994, the Court of Common Pleas of Allegheny County, Pennsylvania granted summary judgment in favor of Polymer, Thrift Drug and Dr. Letham on the grounds that Petitioners' claims against these parties were preempted by the Medical Device Amendments.

Petitioners filed a notice of appeal to the Superior Court of Pennsylvania from this order. Said notice of appeal stated: "Notice is hereby given that the Plaintiffs, above named, hereby appeal to the Superior Court of

Pennsylvania from the Order granting Summary Judgment to the Defendant(s), **Polymer Technology Corp. and Thrift Drug, Inc.** entered in this matter on the 20th day of October, 1994. This order has been entered into the docket as evidenced by the attached copy of the docket entry." (emphasis added).

While Polymer and Thrift Drug are named in the notice of appeal, Dr. Letham is not named. Furthermore, in the argument presented to the Superior Court of Pennsylvania, the Petitioners completely failed to address the causes of action brought individually against Dr. Letham. *See* Opinion of the Superior Court of Pennsylvania dated December 5, 1995, App. 6. The only time the claims against Dr. Letham were mentioned was in the Petitioners' reply brief where they argued that Dr. Letham could be held strictly liable under Pennsylvania law. *Id.* The Superior Court found this argument to be totally without merit and held that Dr. Letham was not subject to strict liability under Pennsylvania law. *Id.* As a result, the Pennsylvania Superior Court held that the Petitioners had ". . . . waived any claims that the trial court erred in granting summary judgment in favor of Dr. Letham on the negligence and breach of implied warranty causes of action for failure to argue them in their brief." *Id.*

Petitioners, in their Petition for Writ of Certiorari, do not challenge the Superior Court's finding of waiver with respect to their claims against Dr. Letham. They also do not challenge the Superior Court's conclusion that Dr. Letham cannot be held strictly liable under Pennsylvania law. Rather, the only issue which they raise is whether their state law causes of action are pre-empted by 21

U.S.C. § 360k(a). Since the judgment in favor of Dr. Letham was not based on preemption, but on waiver and the application of Pennsylvania state law, Dr. Letham is not a proper party to this Petition for Writ of Certiorari and Certiorari should be denied as to him.

CONCLUSION

Therefore, Respondent, Dr. James H. Letham, respectfully requests that the Petition for Writ of Certiorari be denied.

Respectfully submitted,

PIETRAGALLO, BOSICK & GORDON

ROBERT J. BEHLING, Esquire
BRIAN S. KANE, Esquire
JEANETTE H. HO, Esquire

One Oxford Centre, 38th Floor
Pittsburgh, PA 15219

(412) 263-2000

Counsel for Respondent, Dr. James H. Letham

APPENDIX

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
-CIVIL DIVISION-

DEBORAH EDDY and THOMAS EDDY, Plaintiffs, v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG INC., and DR. JAMES H. LETHAM, O.D. Defendants.	No. GD 92-16038 Code No. 004 DECLARATION OF WILLIAM GLEASON, O.D., IN SUPPORT OF DEFENDANTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, DRUG, INC.'S MOTION FOR SUMMARY JUDGMENT Filed on behalf of Polymer Technology Corporation and Thrift Drug, Inc. Counsel of Record for this party: Kerry A. Kearney Pa. I.D. No. 20120 REED SMITH SHAW & McCLAY Firm I.D. No. 234 435 Sixth Avenue Pittsburgh, PA 15219 (412) 288-3046

IN THE COURT OF COMMON PLEAS OF
ALLEGHENY COUNTY, PENNSYLVANIA
-CIVIL DIVISION-

DEBORAH EDDY and THOMAS EDDY, Plaintiffs, v. POLYMER TECHNOLOGY CORPORATION, THRIFT DRUG INC., and DR. JAMES H. LETHAM, O.D. Defendants.	No. GD 92-16038 Code No. 004 DECLARATION OF WILLIAM GLEASON, O.D., IN SUPPORT OF DEFENDANTS POLYMER TECHNOLOGY CORPORATION AND THRIFT DRUG, DRUG, INC.'S MOTION FOR SUMMARY JUDGMENT

I, William Gleason, O.D., declare:

1. I have been employed by Polymer Technology Corporation ("Polymer") since October 1987. From October 1, 1987, until May 1991, I served as Polymer's Director of Clinical and Regulatory Affairs. From May 1991 until January 1994 I was Polymer's Director of Product Development and Quality Affairs. Since January 1994, I have been Polymer's Director of Quality and Regulatory Affairs.

2. As Director of Quality and Regulatory Affairs, my responsibilities include overseeing Polymer's dealings with the Federal Food and Drug Administration ("FDA") in gaining FDA approval of Polymer's products and maintaining the approval status of those products. I am knowledgeable in regulatory practices and various governmental requirements for medical devices, including FDA regulations, concerning approval of medical

devices, post-approval surveillance and good manufacturing practices. I participate on product development teams to determine regulatory requirements for new Polymer products, review safety and efficacy information generated on Polymer products, submit applications to the FDA for pre-market approval for new Polymer products, and respond to FDA review or requests for clarification and additional information during the regulatory review process. Additionally, my department is responsible for reviewing and approving all Polymer label changes to insure compliance with FDA regulations and I manage all approved Polymer products to insure compliance with current regulatory requirements. I am familiar with all documentation regarding FDA approval of Polymer's products.

3. Polymer manufactures and distributes the Boston® line of contact lens solutions designed for use with rigid gas permeable ("RGP") contact lenses. The Boston® Solutions include Boston® and Boston Advance® Cleaners and Conditioning Solutions. The Boston® line of products has been on the market since 1983. The Boston Advance® Cleaner ("Cleaner") has been formulated for daily cleaning of RGP lenses to remove surface deposits which build up during lens wear. The Boston Advance® Conditioning Solution ("Solution") has been formulated to disinfect RGP lenses after cleaning and rinsing and to enhance the wettability characteristics of RGP lenses.

4. The attached package insert and labeling for the Boston Advance® Cleaner recommends that the user "rub lens carefully with several drops of Boston Advance® Cleaner in the palm of your hand for twenty (20) seconds" and then "rinse off thoroughly with fresh

tap water." The directions then tell the user to "place lens in storage case and cover with a fresh supply of Conditioning Solution. Soak for at least 4 hours or overnight before wearing." A true copy of the package insert for the Boston Advance® Cleaner is attached as "Exhibit A." The package insert and labeling for the Boston® Conditioning Solution states that after disinfection with the Conditioning Solution for at least four hours or overnight the user should "reapply fresh Boston Advance® Conditioning Solution if desired and insert." A true copy of the package insert for the Boston Advance® Conditioning Solution is attached as "Exhibit B."

5. In 21 C.F.R. 886.5918 (1993), the FDA classifies rigid gas permeable contact lens solutions as Class III medical devices pursuant to the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act. Pub. L. 94-295, § 2, 90 Stat. 574, amending 21 U.S.C. § 301 *et seq.* (codified at 21 U.S.C. § 360c *et seq.*). Both the Cleaner and the Solution are RGP lens solutions, classified by the FDA pursuant to 21 C.F.R. 886.5918 as Class III medical devices:

> (a) A rigid gas permeable contact lens solution is a device intended to clean, disinfect, wet or store a rigid gas permeable contact lens.
>
> (b) *Classification.* Class III.
>
> (c) *Date PMA or notice of completion of a [Product Development Protocol] is required.* . . . An approval under section 515 of the act is required before this device may be commercially distributed.

21 C.F.R. § 886.5918.

6. Under 21 C.F.R. § 886.3, the FDA requires that the Solution and Cleaner, as Class III medical devices, receive pre-market approval ("PMA") to determine the safety and efficacy of these solutions prior to being marketed or sold by Polymer:

> a device in this part [of the regulation] that is classified into class III (premarket approval) shall not be commercially distributed . . . unless the manufacturer has an approval under section 515 of the act . . . An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval for the device or declaring completed a product development protocol for the device.

21 C.F.R. § 886.3.

7. On September 14, 1989, Polymer submitted detailed applications to the FDA seeking pre-market approval for the Cleaner and detailed applications for the Solution on November 3, 1988. The applications disclosed the proposed directions for use of these products, including directions concerning rinsing the RGP lenses with tap water after use of the Cleaner and prior to disinfection with the Solution. As part of the PMA application process for the Cleaner and Solution, the FDA considered the propriety of all the labeling associated with the products, including tap water rinsing. The cover letters submitted with the applications are attached as "Exhibit C" and "Exhibit D."

8. The PMA applications for the Cleaner and the Solution included information regarding product specifications, intended use, manufacturing methods, and data

from clinical studies conducted of patients using the Boston® Solutions. As part of the review process, the FDA referred Polymer's original PMA applications to the FDA Ophthalmic Devices Panel of the Center of Devices and Radiological Health for review by experts in the ophthalmology.

9. In a letter dated June 1, 1989, the FDA approved a supplemental PMA application for the Solution, stating that "based upon the information submitted, the PMA supplement is approved subject to the conditions described", thereby permitting the Solution to be marketed as a Class III medical device. (Attached as "Exhibit E".) In a letter dated May 3, 1990, the FDA approved the PMA application for the Cleaner, permitting it also to be marketed as a Class III medical device. The approval letter states that "you may begin commercial distribution of the device upon receipt of this letter." (Attached as "Exhibit F".)

10. The FDA approved the PMA application for the original formula Boston® Cleaner and the original formula Boston® Conditioning Solution on November 17, 1983. In this original 1983 PMA, the FDA approved tap water rinsing of RGP lenses.

11. Rinsing of the RGP lenses in tap water prior to disinfection with Boston® products has been approved as safe and effective through the PMA approval process by the FDA three times (1987, 1989, and 1990) since the original 1983 approval.

12. At all times since the products were approved by the FDA as Class III medical devices, Polymer has maintained FDA approval for the Cleaner, Solution, the

original formula Boston® Conditioning Solution, and original formula Boston® Cleaner, including all labeling and directions for use associated with these products.

I declare under penalty of perjury under the laws of the Commonwealth of Pennsylvania pursuant to 18 Pa.C.S.A. § 4904 that the foregoing is true and correct.

/s/ William J. Gleason, O.D.
William J. Gleason, O.D.
Director of Quality &
Regulatory Affairs
Polymer Technology
100 Research Drive
Wilmington, MA 01887

Date: August 2, 1994

LIST OF EXHIBITS

Exhibit A ....Boston Advance® Cleaner Instructions

Exhibit B.....Boston Advance® Conditioning Solution Instructions

Exhibit C.....PMA Cover Letter for Boston Advance® Cleaner

Exhibit D ....PMA Cover Letter for Boston Advance® Conditioning Solution

Exhibit E.....FDA Approval Letter for Boston Advance® Conditioning Solution

Exhibit F.....FDA Approval Letter for Boston Advance® Cleaner

Boston™
ADVANCE
cleaner
For Rigid Gas Permeable
Contact Lenses
not for use with Soft Lenses

See Package Insert for
Lens Lit, Directions, and
Important Safety Information
10 ml • Sterile • Patent Pending
Lot/Exp. Date

Boston Advance Cleaner 10 ml
PMS 222 Magenta
PMS 874 Gold

CONFIDENTIAL

P 2886

LBOU0101	LABELING APPROVAL 58580	
RI	Alex Sato	Date: 5-4-90
. & D	N/A	Date: —
	J. Pomander	Date: 5-4-90
A	Gale Mercaf	Date: 5/4/90
egal	By N/A	Date: —
tem No.	N/A	Supercedes —

EXHIBIT A

[redacted]

POLY001763

BOSTON ADVANCE™ Cleaner

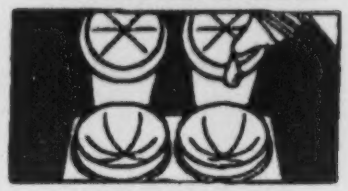
For Fluoro Silicone Acrylate and Silicone Acrylate Rigid Gas Permeable Contact Lenses

DIRECTIONS FOR USE:

1 Wash hands thoroughly.

2 Rub lenses carefully with several drops of BOSTON ADVANCE Cleaner in the palm of your hand for twenty (20) seconds.

3 REMOVE ALL TRACES OF BOSTON ADVANCE CLEANER BY THOROUGHLY RINSING WITH FRESH TAP WATER.



4 Place lens in storage case and cover each lens with a fresh supply of conditioning solution. Soak for at least 4 hours or overnight before wearing.

5 Always keep bottle tightly closed when not in use.

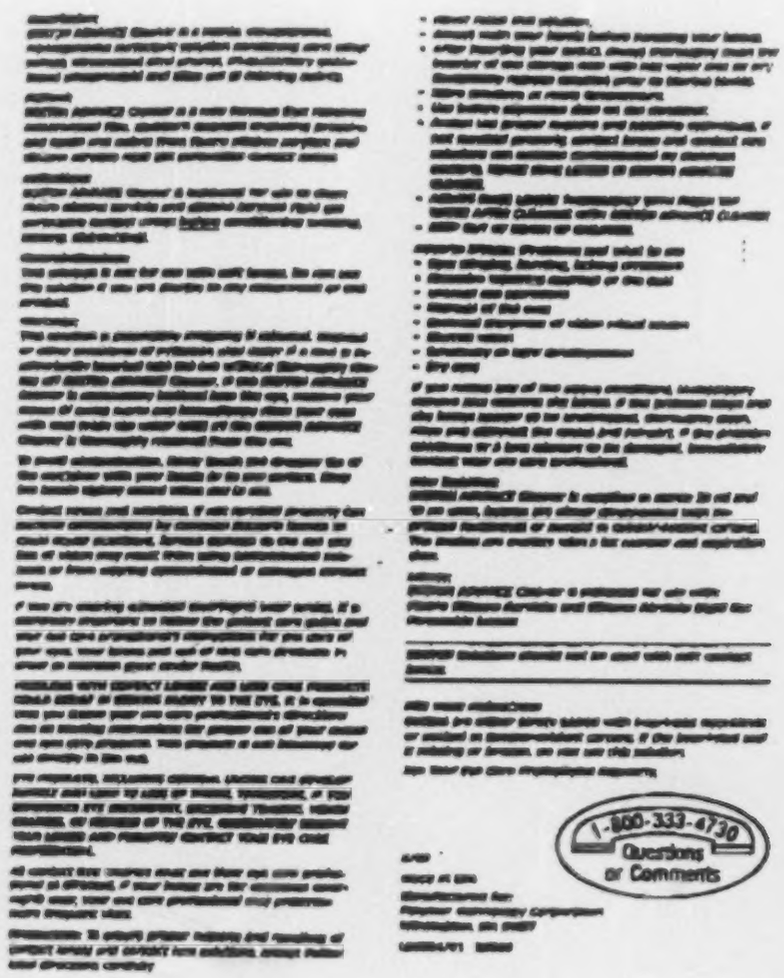
6 Carefully observe warnings and precautions on the following side. Store at room temperature. IMPORTANT: Please read carefully and keep this information for future use.

FRONT

ml
ston Advance Cleaner

DH

POLY001837



BACK

LB6034/01 LABELING APPROVAL 5856		
MKT	L Walworth	Date: 4-20-90
R & D	N/A	Date: —
QA	L Provencher	Date: 4-20-90
RA	Ellen M Beuchler	Date: 4-20-90
Legal	By N/A	Date: —
Item No. N/A		Supercedes —

POLY001836

[redacted]

STON ADVANCE™
CARE SYSTEM

Rigid Gas Permeable
Contact Lenses

POLY00176B

[redacted]

WHY YOU SHOULD USE
BOSTON ADVANCE™
Solutions

[redacted]

DIRECTIONS
BOSTON™
Cleaner

[redacted]

BOSTON ADVANCE™
Conditioning Solution

[redacted]

BOSTON ADVANCE™
Reconditioning Drops

[redacted]

Ask For
BOSTON™ ADVANCE
Solution

[redacted]

BOSTON ADVANCE SOLUTIONS
SHOULD NOT BE USED WITH
SOFT CONTACT LENSES

CAUTION: BOSTON Cleaner will irritate your eyes and must be removed from lenses by thorough rinsing after cleaning. The lenses should be conditioned by soaking in BOSTON ADVANCE Conditioning Solution for at least 4 hours (or overnight) before wearing.

[redacted]

Printed in U.S.A.

IMPORTANT
SAFETY INFORMATION

[redacted]

P 290

LB1103/10 S837
Insert - US Kits

CONFIDENTIAL

LABELING APPROVAL S837

VQT	[redacted]	Date: 1-5-89
R & D	N/A	Date: —
QA	[redacted]	Date: 1-10-89

EXHIBIT B

CONFIDENTIAL

Boston
ADVANCE
Conditioning Solution

For Rigid Gas Permeable Contact Lenses
See package insert

Wetting • Soaking • Disinfecting
1 fluid oz. (30 ml)
Sterile • Patented

DIRECTIONS:
- Wash hands with mild soap.
- Clean your lenses with BOSTON® or BOSTON ADVANCE® Cleaner. RINSE THOROUGHLY WITH FRESH TAP WATER, then place lenses in storage case and fill the case with BOSTON ADVANCE® Conditioning Solution. Soak for at least 4 hours for overnight before wearing.
- After removing the lenses from the storage case, reapply fresh BOSTON ADVANCE® Conditioning Solution if desired and insert.
- Clean interior of storage case with hot water and air dry. Completely replace solution every day.
- To avoid contamination, never touch the dropper tip or the container with your hands or to any surface.
- Discard solution 90 days after opening. Record date opened in space below. *See package insert for details.*

Date opened:

EXHIBIT B

POLY00176I

P 2881

Boston Advance
Label 200
6000. Pack

L80094/03 LABELING APPROVAL 59215

MKT		Date: 4-26-8
R & D	N/A	Date: —
QA	G. Provencher	Date: 4-25-90
RA	Ellen M Beucler	Date: 4-25-90
Legal	By N/A	Date: —
Item No.	N/A	Supercedes —

8/20/37

L60094/01 LABELING APPROVAL # P 345

MKT	N. Caruso	Date: 6-21-89
R & D	N/A	Date: —
QA		Date:
RA		Date: 6/23/89
Legal	N/A	Date: —
Item No.	N/A	Supercedes —

- 800 %
Label-30ml BOSTON ADVANCE™ Conditioning Soln. - Bull-Starter Kit
- L60094/01 51345

PMS 072 Blue, PMS 874 Gold

P 2883

P.21/37

BOSTON ADVANCE™ Conditioning Solution

For Fluoro Silicone Acrylate and Silicone Acrylate Rigid Gas Permeable Contact Lenses (As listed)

DIRECTIONS FOR USE:

1 Wash hands thoroughly.

2 Remove lenses from storage case, reapply fresh BOSTON ADVANCE Conditioning Solution if desired and insert.

3 Thoroughly clean interior of storage case with hot water and air dry. Completely replace solution prior to storing lenses every time. Soak for at least 4 hours or overnight before wearing.

4 To avoid contamination, always keep bottle tightly closed when not in use.

5

6

FRONT

POLY001839

120 ml US Trade / Bulk Pack
Boston Advance Cond. Sol.
Print F+B

PMS 072 Bl
Black

BOSTON ADVANCE™ Conditioning Solution

DESCRIPTION:
BOSTON ADVANCE Conditioning Solution has been specifically formulated for use with fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses. It contains a patented hydrophilic polyelectrolyte, and a cationic cellulose derivative polymer. As a wetting agent, that binds to the surface of the lens enhancing wettability and maintaining surface ionic charges. It is a sterile, buffered, slightly hypertonic solution with polyelectrolyte properties (Sodium and edetate disodium dihydrate as preservatives).

ACTIONS:
BOSTON ADVANCE Conditioning Solution is a new formula that optimizes the wettability characteristics of rigid gas permeable contact lenses. It also reduces friction against the corneal and harnesses particulate matter that may cause irritation and discomfort. BOSTON ADVANCE Conditioning Solution contains a new disinfecting agent which is effective in destroying harmful microorganisms on the surface of rigid gas permeable lenses stored and in contact lens cases.

INDICATIONS:
BOSTON ADVANCE Conditioning Solution is indicated for disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses as listed in the labeling.

WARNINGS:
This solution is not for use with soft lenses. Do not use this solution if you are hypersensitive to any components of this product. To avoid contamination, never touch the dropper tip of the container with your hands or to any surface.

Contact lenses and solutions, if not handled properly can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and loss of vision may result from using contaminated solutions or from wearing contaminated or damaged contact lenses. Rinsing and then rubbing the lens with solution, before each removal, is recommended by some eye care professionals. BOSTON ADVANCE Conditioning Solution will be discussed further in class.

If you are wearing antibiotics ointments near lenses, it is extremely important to follow the patient care guide and your eye care professional's instructions for the care of both your lenses and lens care products, in order to maintain good ocular health.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follows your eye care professional's directions and all labeling instructions for proper use of your lenses and lens care products.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PROFESSIONAL.

All contact lens wearers should see their eye care professional as directed. If your lenses are not extended wear/prescribed wear, your eye care professional may prescribe more frequent visits.

PRECAUTIONS: To ensure proper hygiene and handling of contact lenses and contact lens solutions, always follow lens directions carefully.

- Never reuse this solution
- Always keep the bottle tightly closed when not in use.
- Always wash your hands before handling your lenses.
- After inserting your lenses, always thoroughly clean the footpiece of the storage case with hot water and air dry. Consistently replace solution prior to storing lenses every day.
- Store solutions at room temperature.
- Use before expiration date on the container
- Always use proper hygiene and handling procedures. If not handled properly, contact lenses and contact lens solutions can become contaminated by common bacteria.
- SOAK LENSES IN BOSTON ADVANCE CONDITIONING SOLUTION, NEVER SOAK LENSES IN SALINE OR BOSTON ADVANCE CLEANER.
- ALWAYS RINSE LENSES THOROUGHLY WITH FRESH RUB WASH AFTER CLEANING WITH BOSTON OR BOSTON ADVANCE CLEANER. CONDITION LENSES WITH BOSTON ADVANCE CONDITIONING SOLUTION, SOAK FOR AT LEAST 4 HOURS (OR OVERNIGHT) BEFORE WEARING.
- KEEP OUT OF REACH OF CHILDREN.

The following problems may occur:

- Eyes stinging, burning, itching sensation
- Excessive watering (tearing) of the eyes
- Unusual eye sensitivity
- Redness of the eyes
- Reduced sharpness of vision (visual acuity)
- Blurred vision
- Sensitivity to light unbearable
- Dry eyes

If you notice any of the above conditions, immediately remove and examine the lenses. If the problem stops and the lenses appear to be undamaged, thoroughly clean, rinse and disinfect the lenses and reinsert. If the problem continues or a lens appears to be damaged, immediately contact your eye care professional.

HOW SUPPLIED:
BOSTON ADVANCE Conditioning Solution is supplied in sterile 4 fluid ounce (120 ml) and one fluid ounce (30 ml) bottles. Bottles are shrink-wrapped with tamper-evident neckbands or packaged in tamper-evident cartons. The packet are marked with a lot number and expiration date.

LENSES:
BOSTON ADVANCE Conditioning Solution is indicated for use with:
Fluoro Silicone Acrylate lenses:
BOSTON® EQUALITY™
Silicone Acrylate Lenses:
BOSTON®, Menicon®, Paragon CRT®, Optacryl®, Optacryl HEP®, Optacryl HDK®, Optacryl HDS®, Optacryl HDT®, Optacryl HDT ELITE®

BOSTON Solutions should not be used with soft contact lenses.

FOR YOUR PROTECTION:
Success and comfort with contact lenses depend on proper care and handling. Follow the directions and labeling instructions for the solutions you use. Consult your eye care professional if you have any questions about your lenses or lens care products.

See your Eye Care Professional frequently.

Made in the USA
Manufactured for:
Polymer Technology Corporation
Wilmington, MA 01887
U.S. Patent No. 4,820,352

BACK

LBloM1101	LABELING APPROVAL 59181	
MKT	[signature]	Date: 5-2-90
R & D	N/A	Date: —
QA	[signature]	Date: 4-30-90
RA	[signature]	Date: 4-25-90
Legal By	N/A	Date: —
Item No.	N/A	Supercedes —

POLY001838

15a

EXHIBIT C

POLYMER TECHNOLOGY CORPORATION
[LOGO] 100 RESEARCH DRIVE • WILMINGTON
(608) 658-6111 • MASSACHUSETTS

September 14, 1989

RE: PMA Application
for the BOSTON™ Cleaner II

FDA
Center for Devices and Radiological Health
PMA – Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sirs:

Enclosed herein, please find six (6) copies of the original PMA Application for the BOSTON™ Cleaner II for use in the care regimen for fluoro-silicone-acrylate and silicone-acrylate rigid gas permeable contact lenses.

Generic Name: Cleaning Solution For Rigid Gas Permeable Contact Lenses

Trade Name: The BOSTON™ Cleaner II

The BOSTON™ Cleaner II is indicated for daily or periodic cleaning of fluoro-silicone-acrylate and silicone-acrylate rigid gas permeable contact lenses. In addition, when combined with the BOSTON™ Conditioning Solution or the BOSTON™ Conditioning Solution II as in the BOSTON™ Care System, the system is proven to be an effective disinfecting agent. The BOSTON™ Cleaner II is available in 5 mL, 10 mL, 15 mL and 30 mL units. The shelf-life of this product is seven (7) months. Shelf-like extensions and qualifications of alternate bottle resins

will be performed in accordance with 1985 FDA Solution Guidelines.

During the development of this product the BOSTON™ Cleaner II was referred to as the SPD-KST1 Lipid Cleaner. This application and accompanying reports contain references to both names. According to 21 CFR 25.23 (c) this product is excluded from the environmental impact requirement.

This application is sponsored by Polymer Technology Corporation of Wilmington, Massachusetts. The manufacturing site of the BOSTON Cleaner II is Bausch & Lomb Solutions Plant in Greensville, South Carolina.

CONFIDENTIALITY

The information contained in this document is exempt from disclosure pursuant to section 812.38 of Title 21 of the Code of Federal Regulations and to Section 552 of Title 5 of the United States Code. In addition, specific information marked CONFIDENTIAL is considered to be Proprietary Information belonging to Polymer Technology Corporation which may not, under any circumstances, be disclosed.

If you should require additional information or have questions, please do not hesitate to contact me.

Sincerely,

/s/ Ellen M. Beueler
Ellen M. Beueler
Clinical and Regulatory
Affairs Associate

emb

EXHIBIT D

POLYMER TECHNOLOGY CORPORATION
[LOGO] 100 RESEARCH DRIVE • WILMINGTON
(608) 658-6111 • MASSACHUSETTS

November 3, 1988

RE: PMA Application
for the BOSTON™ Conditioning
Solution II and The BOSTON™
Reconditioning Drops II.

FDA
Center for Devices and Radiological Health
PMA – Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sirs:

Enclosed herein, please find six (6) copies of the PMA Application for the BOSTON™ Conditioning Solution II and the BOSTON™ Reconditioning Drops II when used as the care regimen for rigid gas permeable contact lenses.

Generic Name:	Wetting and soaking solution for rigid gas permeable contact lenses
Trade Name:	The BOSTON™ Conditioning Solution II and The BOSTON™ Reconditioning Drops II

The BOSTON™ Conditioning Solution II and the BOSTON™ Reconditioning Drops II, hereafter referred to as the BOSTON CJP1 Solutions, are designed to be effective conditioning and rewetting agents for the care and maintenance of rigid gas permeable contact lenses. In

addition, when combined with the BOSTON™ Cleaner as in the BOSTON™ Care System, the conditioner is proven to be an effective disinfecting agent. The conditioning solution is intended for wetting and soaking the contact lenses. The reconditioning drops are intended to be instilled directly into the eye to enhance lens wettability characteristics and reduce friction against the cornea while the lens is being worn by the patient.

These solutions are similar to the currently marketed BOSTON™ Conditioning Solution and BOSTON™ Reconditioning Drops. The difference is a decrease in the viscosity and a change in the preservative system from chlorhexidine gluconate (CHG) to polyaminopropyl biguanide (PAPB). This preservative is also referred to as polyhexamethylene biguanide (PHMB) or polyhexamethylene diguanide (PHMD). According to 21 CFR 25.23 (c) this product is excluded from the environmental impact requirement.

This application is sponsored by Polymer Technology Corporation of Wilmington, Massachusetts. The manufacturing site of the BOSTON CJP1 Solutions is Bausch & Lomb Solutions Plant in Greenville, South Carolina.

If you should require additional information or have questions, please do not hesitate to contact me.

Sincerely,

/s/ William J. Gleason (emb)
William J. Gleason, O.D.
Director, Clinical and
Regulatory Affairs

emb

EXHIBIT E

[LOGO]
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

William J. Gleason, O.D.
Director, Clinical and Regulatory Affairs
Polymer Technology Corporation
100 Research Drive
Wilmington, Massachusetts 01887

RE: P820070/S14
THE BOSTON™ Conditioning Solution and
THE BOSTON™ Reconditioning Drops
Filed: November 9, 1988
Amended: April 24, and 25; and
May 3, 23, and 25, 1989

Dear Dr. Gleason:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval to decrease the viscosity and change the preservative system from chlorhexidine gluconate to polyaminopropyl biguanide for the above referenced devices. THE BOSTON™ Conditioning Solution, as modified, will be marketed under the trade name BOSTON™ Conditioning Solution II and supplied in 30 ml and 120 ml plastic

bottles. THE BOSTON™ Reconditioning Drops, as modified, will be marketed under the trade name BOSTON™ Reconditioning Drops II and supplied in a 10 ml plastic bottle.

The BOSTON™ Conditioning Solution II is indicated for disinfecting and soaking after cleaning and rinsing of silicone-acrylate and fluoro-silicone-acrylate rigid gas permeable contact lenses (as listed in the labeling). The BOSTON™ Reconditioning Drops II is indicated for use directly in the eye to lubricate and rewet silicone-acrylate and fluoro-silicone-acrylate rigid gas permeable contact lenses (as listed in the labeling) during lens wear.

Based upon the information submitted, the PMA supplement is approved subject to the conditions described in the "Conditions of approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The expiration dating for the BOSTON™ Conditioning Solution II and BOSTON™ Reconditioning Drops II has been established and approved at 6 months. This is to advise you that the protocol used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.38(a)(8).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning the approval of this supplemental application, please contact Ms. Alice Yoza or Mr. David M. Whipple at (301) 427-7940.

Sincerely yours,

/s/ Richard E. Lippman
Richard E. Lippman,
O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure 1

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for

Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Advertisement. No advertisement and other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Premarket Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.

Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. *Two copies* identified as *"Annual Report"* and bearing the applicable PMA reference number are to be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

Adverse Reaction and Device Defect Reporting. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit *3 copies* of a written report identified as an *"Adverse Reaction Report"* or *"Device Defect Report"*, as applicable, to the Food and Drug Administration, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910 *within 10 days* after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable in the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occuring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that *could not* cause or contribute to death or

serious injury but *are not* correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

Reporting under the Medical Device Reporting (MDR) Regulation. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including *in vitro* diagnostic devices, report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of its marketed devices (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and that

the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to reoccur.

The conditions of approval accompanying PMA approval orders may require that the same events subject to reporting under the MDR Regulation must also be included in periodic reports to the PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the conditions of approval for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Device Monitoring Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910
Telephone (301) 427-7500

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and a FDA publication entitled, "An Overview of the Medical Device Reporting Regulation", are available by written request to the above address or by telephoning (301) 427-8100.

EXHIBIT F

[LOGO]
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 3 1990

Ms. Ellen M. Beucler
Clinical and Regulatory Affairs Associate
Polymer Technology Corporation
100 Research Drive
Wilmington, Massachusetts 01887

RE: P890054
BOSTON™ Cleaner II
Filed: September 15, 1989
Amended: November 24, 1989; and February 24, March 23, and April 24, 1990

Dear Ms. Beucler:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BOSTON™ Cleaner II. This device is indicated for use to clean fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses before conditioning (wetting, soaking, disinfecting). The solution is to be marketed in 5mL, 10 mL, 15 mL and 30 mL bottle sizes. The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for this device has been established and approved at 7 months. This is to advise you that the protocol used to establish this expiration dating is considered an approval protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at the CDRH. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850-4302

If you have any questions concerning this approval order, please contact Ms. Eleanor M. Felton or Mr. David M. Whipple at (301) 427-1080.

Sincerely yours,

/s/ D R West
for Robert L. Sheridan
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE 1

REVISED: September 12, 1989

CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 1390 Piccard Drive, Rockville, Maryland 20850.

Advertisement. No advertisement and other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device.

If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Pre-market Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.

Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. *Two copies* identified as *"Annual Report"* and bearing the applicable PMA reference

number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Drive, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

The "Conditions of Approval" accompanying PMA approval orders may require that the same events subject to reporting under the MDR Regulation must also be included in periodic reports to the PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and

identified with the PMA reference number to the following office:

Device Monitoring Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850
Telephone (301) 427-1144

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation", are available by written request to the above address or by telephoning (301) 427-1140.